IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
ANDERSON DIVISION

POLY-MED, INC., Plaintiff, v. NOVUS SCIENTIFIC PTE. LTD, NOVUS SCIENTIFIC, INC. and NOVUS SCIENTIFIC AB, Defendants.	Civil Action No.: 8:15-cv-01964-JMC **ORDER AND OPINION**

Plaintiff Poly-Med, Inc. ("Poly-Med" or "PMI") filed this action seeking monetary damages, injunctive and equitable relief from Defendants Novus Scientific Pte. Ltd. ("Novus Singapore"), Novus Scientific, Inc. ("Novus USA"), and Novus Scientific AB ("Novus Sweden") (collectively "Novus Defendants") as a result of alleged violations of the parties' business agreement. (ECF No. 181.)

This matter is before the court pursuant to Novus Defendants' Motion for Summary Judgment Regarding PMI's South Carolina Unfair Trade Practices Act ("SCUTPA") Claim. (ECF No. 273.) Poly-Med opposes the Motion in its entirety. (ECF No. 293.) For the reasons set forth in detail below, the court **GRANTS** Novus Defendants' Motion for Summary Judgment.

I. RELEVANT BACKGROUND TO PENDING MOTION

Founded by Dr. Shalaby W. Shalaby in 1993, Poly-Med is a South Carolina corporation with its principal place of business at 6309 Highway 187, Anderson, South Carolina 29625. (ECF Nos. 1 at 1 ¶ 1 & 104-1 at 1 ¶ 3.) "Poly-Med designs, develops, and manufactures products and materials [out of bio-absorbable and biodegradable polymers] for use in medical,

pharmaceutical and biotechnology applications." (ECF No. 1 at 3 ¶¶ 8–9; *see also* ECF No. 104-1 at 1 ¶ 3.) "Poly-Med has numerous trademarks, more than one hundred thirty patents and patent applications and has successfully licensed and manufactured technologies found in many commercially available medical applications." (ECF No. 104-1 at 2 ¶ 5.) "In addition to creating its own products and materials, Poly-Med offers manufacturing services and consulting, analytic and research and development services to a variety of firms in the medical, pharmaceutical and biotechnology industries." (*Id.* at ¶ 6.)

In December 2004, a Swedish company called Radi Medical Systems AB ("Radi") applied for a patent entitled "Mesh Implant for Use in Reconstruction of Soft Tissue Defects." (ECF No. 126-2 at 2 ¶ 4.) Radi's goal was "to commercialize the invention in order to reconstruct soft tissue defects to promote optimal healing and tissue restoration." (*Id.*) Even though Radi "possessed the background and know-how regarding degradable polymers, polymerization, and processing into final medical devices," it "did not have all of the physical equipment needed." (*Id.* at 2–3 ¶ 5.)

In early 2005, Poly-Med began negotiations with and eventually entered into a Sale of Materials and License Agreement (the "Agreement") with Radi on or about June 8, 2005. (ECF No. 104-1 at 2 ¶ 7–4 ¶ 15.) The Agreement required Poly-Med to "develop and manufacture at least six different types of Absorbable Composite Meshes[1] for sale to and use by Radi" in

[1] The Agreement defined "Absorbable Composite Mesh" as "any special absorbable composite fibrous constructs absorbed by the human body for specific use in herniated tissues which (i) has not been previously sold or licensed to any other person or entity for product development or commercial application that conflicts with its use by RADI AB in its hernial mesh application; (ii) that falls within the scope of any valid claim of any POLY-MED patent or patent application; or (iii) is manufactured under or using a process that falls within the scope of any Valid Claim of any POLY-MED Patent or POLY-MED Patent Application; or (iv) comprises or makes use of POLY-MED Know-How; or (v) is manufactured under, or using a process constituting, POLY-MED Know-How." (ECF No. 126-1 at 3 ¶ 1(f).)

"hernial repair products." (ECF No. 126-1 at 4 ¶ 2(a).) From the group of six proprietary, absorbable surgical meshes, Radi was to select one or two which it believed "hold the most promise for purposes of developing RADI Products . . . ." (*Id.* at 7 ¶ 4(a).) Radi would then "have the exclusive right to use any Select Absorbable Composite Mesh used by it in the development, manufacture, sale and distribution of its medical products . . . ." (*Id.* at 8 ¶ 5.) Per the terms of the Agreement, "Radi was to compensate Poly-Med for its development work, manufacturing and production of the mesh that took place exclusively in South Carolina." (ECF No. 35-2 at 2 ¶ 11.) In February 2007, Radi selected one prototype surgical mesh which was then developed into a medical device called TIGR®Matrix Surgical Mesh ("TIGR®Mesh"). (ECF No. 126-2 at 4–5 ¶ 14.) In December 2008, Radi transferred its rights under the Agreement to Novus Singapore.[2] (ECF No. 126-5 at 2 ¶ 4.)

Upon receipt of an application, the U.S. Food and Drug Administration ("FDA") issued 510(k)[3] clearance of TIGR®Mesh on January 25, 2010, "for surgical use in 'reinforcement of soft tissue where weakness exists.'" (ECF No. 126-2 at 5 ¶ 17.) Poly-Med helped Novus Defendants obtain FDA approval of the TIGR®Mesh by (1) maintaining their Device Master Record[4] ("DMR") in South Carolina and (2) allowing them to use "confidential and proprietary

[2] Poly-Med contends that it was told by Radi that the Agreement was assigned to Novus Singapore, but a "Transfer Agreement" provided to Poly-Med reveals that the Agreement transferred from Radi to Novus USA. (*See* ECF Nos. 35-2 at 3 ¶¶ 13, 15 & 35-3 at 1.)

[3] "A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA." FDA Premarket Notification 510(k), http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm (last visited Aug. 22, 2018). "Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims." *Id.*

[4] "A Device Master Record is a compilation of all the instructions, drawings and other records that must be used to produce a product." (ECF No. 38-3 at 4 ¶ 25.) "The term is used in Quality Management Systems that cover product design and production." (*Id.*) "Under FDA

information located in South Carolina and substantial consultation, testing and assistance." (ECF No. 38-3 at 4 ¶¶ 19, 25.) After receiving 510(k) clearance, Novus Singapore began marketing and selling TIGR®Mesh. (ECF No. 126-5 at 2 ¶ 5.)

On September 27, 2010, Waleed Shalaby, Poly-Med's Chief Science Officer ("CSF"), sent an e-mail to its then President, David Shalaby,[5] in which the CSF observed that a lawyer needed to be contacted because Novus "Defendants were making, selling, and/or using the Medical Device for TRAM flap/breast reconstruction surgery[6]—. . . an application other than hernia repair." (ECF No. 209 at 7 (referencing ECF No. 209-1 at 1).) In response to this information, Poly-Med told Novus Defendants that "it objected to commercialization of the TIGR®Mesh as a 'surgical' mesh rather than a 'hernia' mesh" and allegedly demanded "firm commitments by Novus defendants on further orders for production at substantially increased prices." (ECF No. 104-1 at 16 ¶ 62; *see also* ECF No. 126-5 at 2 ¶ 7.) Then, on September 30, 2010, Poly-Med was informed by a consultant that "it could be inferred from the Novus website that the company is indicating its use for 'soft tissue repair'" and that "if Novus is indeed promoting its use beyond hernia repair, it could be argued that they have violated the terms of the license agreement and it could thus be terminated." (ECF No. 209 at 8 (quoting ECF No. 209-2 at 6 & 7).) On December 22, 2010, Poly-Med sent a letter to Novus Defendants containing the following language:

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regulations, a DMR must be maintained by the manufacturer of any medical device for use in humans." (*Id.* at 4–5 ¶ 25.)

[5] In August 2010, David Shalaby replaced his father as President of Poly-Med. (ECF No. 104-1 at 16 ¶ 61.)

[6] In a TRAM flap procedure (or abdominal wall reconstruction surgery), a section of the abdomen wall is removed and used in breast reconstruction and the mesh is used to repair the hole in the abdomen wall." (ECF No. 104-1 at 16 ¶ 62.)

> Novus has commercialized the TIGR hernia mesh as a 'surgical mesh' when our agreement clearly identifies product licensure by Novus as a 'hernia' mesh only. We believe this to be a serious issue that needs to be addressed by Novus immediately.

(ECF No. 209-3 at 5.)

On or about February 27, 2013, Novus Singapore transferred its interest in the Agreement to its Swedish sister company, Novus Sweden. (ECF No. 126-8 at 1 ¶ 2.) "Since August 2014, using its own manufacturing procedures, Novus Sweden has manufactured TIGR®Matrix Surgical Mesh in its own production facilities, and has continued to sell TIGR® Matrix Surgical Mesh in accordance with the 510(k) clearance and CE registration." (*Id.* at ¶ 3.) "Novus Sweden has paid and continues to pay royalties to Poly-Med regardless of the end use of TIGR®Matrix Surgical Mesh . . . and regardless of whether Poly-Med or Novus Sweden manufactured the TIGR®Matrix Surgical Mesh." (*Id.* at 2 ¶ 5.) "Poly-Med has accepted royalty payments arising from all end uses." (*Id.*)

On May 8, 2015, Poly-Med filed a Complaint against Novus Defendants alleging four causes of action: breach of contract, tortious interference with contract, violation of the South Carolina Trade Secrets Act, S.C. Code Ann. §§ 39-8-10 to -130 (2016), and violation of the SCUTPA, S.C. Code Ann. §§ 39-5-10 to -560 (2016). (ECF No. 1 at 13–25.) After Novus Defendants answered the Complaint on March 14, 2016, the parties engaged in discovery. On November 22, 2016, the court granted Poly-Med's Motion for Leave to Amend Complaint (ECF No. 118) and it filed its Amended Complaint on November 29, 2016. (ECF Nos. 149, 153.) Thereafter, on July 6, 2017, the court granted Poly-Med's Motion for Leave to Amend and Supplement the Amended Complaint (ECF No. 167) and it filed its Second Amended Complaint on July 10, 2017. (ECF Nos. 179, 181.) In the Second Amended Complaint, Poly-Med alleged

claims against Novus Defendants for breach of contract, tortious interference with contract and violation of the SCUTPA. (ECF No. 181 at 14 ¶ 89–27 ¶ 160.)

On June 13, 2018, Novus Defendants moved for partial summary judgment on Poly-Med's SCUTPA cause of action. (ECF No. 273.) After the parties submitted their Response in Opposition (ECF No. 293) and Reply in Support (ECF No. 304), the court heard argument from the parties on this matter on August 9, 2018. (ECF No. 357.)

II. JURISDICTION

The court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332(a) based on Poly-Med's allegations that the action is between citizens of different states and/or countries and the amount in controversy is in excess of $75,000.00, exclusive of interest and costs. (ECF No. 181 at 1 ¶ 1–2 ¶ 4 & 3 ¶ 11.) Specifically, Poly-Med alleges that it is a South Carolina corporation with its principal place of business in Anderson, South Carolina; Novus Singapore is a Singaporean corporation with its principal place of business in Singapore; Novus USA is a Delaware corporation with its principal place of business in San Diego, California; and Novus Sweden is a Swedish corporation with its principal place of business in Uppsala, Sweden. (*Id.*) In this regard, the court is satisfied that complete diversity exists between the parties and the amount in controversy is sufficient to confer jurisdiction upon the court.

III. LEGAL STANDARD

A. Summary Judgment Generally

Summary judgment should be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is "material" if proof of its existence or non-existence would affect the disposition of the case under the applicable law. *Anderson v. Liberty Lobby Inc.*, 477 U.S. 242,

248–49 (1986). A genuine question of material fact exists where, after reviewing the record as a whole, the court finds that a reasonable jury could return a verdict for the nonmoving party. *Newport News Holdings Corp. v. Virtual City Vision*, 650 F.3d 423, 434 (4th Cir. 2011).

In ruling on a motion for summary judgment, a court must view the evidence in the light most favorable to the non-moving party. *Perini Corp. v. Perini Constr., Inc.*, 915 F.2d 121, 123-24 (4th Cir. 1990). The non-moving party may not oppose a motion for summary judgment with mere allegations or denial of the movant's pleading, but instead must "set forth specific facts" demonstrating a genuine issue for trial. Fed. R. Civ. P. 56(e); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986); *Shealy v. Winston*, 929 F.2d 1009, 1012 (4th Cir. 1991). All that is required is that "sufficient evidence supporting the claimed factual dispute be shown to require a jury or judge to resolve the parties' differing versions of the truth at trial." *Anderson*, 477 U.S. at 249. "Mere unsupported speculation . . . is not enough to defeat a summary judgment motion." *Ennis v. Nat'l Ass'n of Bus. & Educ. Radio, Inc.*, 53 F.3d 55, 62 (4th Cir. 1995).

B. Claims for Violation of the SCUTPA

To establish a SCUTPA claim, a plaintiff must demonstrate that "(1) the defendant engaged in an unlawful trade practice, (2) that the plaintiff suffered actual, ascertainable damages as a result of the defendant's use of the unlawful trade practice, and (3) that the unlawful trade practice engaged in by the defendant had an adverse impact on the public interest." *Network Computing Servs. Corp. v. Cisco Sys., Inc.*, 152 F. App'x 317, 320 (4th Cir. 2005) (quoting *Havird Oil Co. v. Marathon Oil Co.*, 149 F.3d 283, 291 (4th Cir. 1998)). "Conduct that affects only the parties to the transaction provides no basis for a SCUTPA claim." *Morgan v. HSBC Bank USA, N.A.*, 6:13-cv-03593-JMC, 2015 WL 3888412, at *4 (D.S.C. June

24, 2015) (citation omitted).

"An impact on public interest may be shown if the acts or practices have the potential for repetition." *Id.* (citation and quotation omitted). The potential for repetition may be shown in two ways: "(1) by showing the same kind of actions occurred in the past, thus making it likely they will continue to occur absent deterrence; or (2) by showing the company's procedures created a potential for repetition of the unfair and deceptive acts." *Id.* (citation and quotation omitted). However, a "plaintiff must use specific facts to demonstrate that members of the public were or were likely to be affected." *Id.* at *5 (citation omitted). Absent specific facts, a plaintiff is merely offering a speculative claim about adverse public impact. *Jefferies v. Phillips*, 451 S.E.2d 21, 23 (S.C. Ct. App. 1994). A claim under SCUTPA is inadequate where it "fails to allege any specific procedures or business practices that create the potential for repetition." *Ethox Chem., LLC v. Coca-Cola Co.*, No. 12-1682, 2013 WL 41001, at *3 (D.S.C. Jan. 3, 2013).

IV. ANALYSIS

A. The Parties' Arguments

Novus Defendants assert that the court should grant their Motion for Summary Judgment on Poly-Med's SCUTPA claim for 3 reasons. First, Novus Defendants assert that Poly-Med is unable to demonstrate that it sustained any ascertainable damages. (ECF No. 273 at 1.) In support of this assertion, Novus Defendants point out that Poly-Med's expert regarding financial circumstances, Philip Green, expressly is unable to opine in his expert report about any "sustained actual, ascertainable damages" suffered by Poly-Med (*id.* at 4):

> Opinion I: Poly-Med has been irreparably harmed by Novus's unauthorized sales of TIGR® mesh, wrongful filing of patent applications in its own name, and the resulting uncertainty regarding intellectual property rights related to TIGR® mesh. Poly-Med has suffered, and continues to suffer, harm that cannot adequately be compensated by monetary damages and that cannot be reliably measured.

> Opinion II: Even if Poly-Med's damages could be measured, and those damages could adequately compensate Poly-Med for the harm it has suffered, Novus does not appear to have the independent financial ability to satisfy a judgment.
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> Opinion III: Novus has not paid for all its sales of TIGR® mesh for hernia applications under the Agreement. From the documents available to me, I am unable to determine which of Novus's sales were for hernia as opposed to unapproved fields of use. Without further information, I am unable to calculate royalties due.

(ECF No. 273-1 at 5.)

Second, Novus Defendants assert that the SCUTPA claim fails because the alleged conduct only affects the private "parties involved in the litigation," not the general public. (*Id.* at 5 (citing *Uhlig LLC v. Shirley*, C/A No. 6:08-cv-01208-JMC, 2011 WL 1119548, at *8 (D.S.C. Mar. 25, 2011) ("A private dispute between two competitors does not impact the public interest under the [SC]UTPA.") (citation omitted)).) Finally, Novus Defendants contend that because the SCUTPA claim "is based on [] [Poly-Med's] 'hernia only' and 'patent application' breach of contract claims, it is barred by SCUTPA's three-year statute of limitations. (*Id.* at 9 (citing ECF No. 252 at 17 ("For this reason, the court finds that Novus Defendants are entitled to summary judgment on Poly-Med's 'hernia only' and 'patent application' breach of contract claims because these claims are barred by the three (3) year statute of limitations found in S.C. Code Ann. § 15-3-530(1) (2017).")).)

Poly-Med opposes the Motion for Summary Judgment. "Poly-Med acknowledges it cannot be adequately compensated by monetary damages and its sole remedy is equitable relief in the form of a declaration that the Agreement is terminated with later enforcement of the post-termination provisions of the Agreement." (ECF No. 293 at 2.) Poly-Med asserts that Novus Defendants' actions affect the public because (1) their misrepresentations in patent applications constituted a fraud on the U.S. Patent and Trademark Office and the public at large and (2) they sold the mesh for uses not cleared by the FDA (*i.e.*, breast reconstruction surgery). (*Id.* at 3.)

Poly-Med further asserts that its SCUTPA claim is not barred by the three-year statute of limitations because each new alleged violation "starts the statute of limitations on Poly-Med's SCUTPA claims anew."[7] (*Id.* at 4.)

B. The Court's Review

"[A] plaintiff may only bring an action under the SCUTPA 'to recover actual damages.'" *First S. Bank v. Fifth Third Bank N.A.*, 631 F. App'x 121, 126 (4th Cir. 2015) (citing S.C. Code Ann. § 39-5-140; *Fields v. Yarborough Ford, Inc.*, 414 S.E.2d 164, 166–67 (S.C. 1992) (explaining that a plaintiff must prove it suffered "actual damages" to recover under the SCUTPA)). "'Actual damages are when the wrongful act has caused a loss or injury which can be assessed in money, the universal and cardinal principle being that the person injured shall receive compensation commensurate with his loss or injury, and no more.'" *Kapuschinsky v. United States*, 259 F. Supp. 1, 6 (D.S.C. 1966) (quoting *Hutchinson v. Town of Summerville*, 45 S.E. 8, 9 (S.C. 1903)).

Upon its review, the court observes that Poly-Med expressly admits that it does not have actual, ascertainable damages and the purpose of this action is to seek equitable relief.[8] (*E.g.*, ECF No. 293 at 2;[9] ECF No. 381 at 69:20–23.[10]) Therefore, upon consideration of the foregoing, the court finds that Poly-Med as a matter of law cannot sufficiently demonstrate that it has

[7] Poly-Med observes that the court addressed the SCUTPA statute of limitations issue in its April 24, 2018 Order finding that "the SCUTPA statute of limitations begins to run anew with each violation." (ECF No. 293 at 4 (citing ECF No. 252 at 13) (citation omitted).)

[8] An equitable remedy is "a nonmonetary one such as an injunction or specific performance, obtained when available legal remedies, usu[ally] monetary damages, cannot adequately redress the injury." Equitable remedy, *Black's Law Dictionary* (10th ed. 2014).

[9] "Poly-Med acknowledges it cannot be adequately compensated by monetary damages and its sole remedy is equitable relief in the form of a declaration that the Agreement is terminated with later enforcement of the post-termination provisions of the Agreement."

[10] "With regard to Poly-Med's Unfair Trade Practices Act claim, the defendants cite no authority for the position that the defendants can't be liable for a violation where only equitable relief is available."

suffered actual, ascertainable damages as a result of Novus Defendants' alleged use of an unlawful trade practice(s).[11] Accordingly, Novus Defendants are entitled to summary judgment on Poly-Med's claim alleging violation of the SCUTPA.

V. CONCLUSION

Upon careful consideration of the entire record, the court hereby **GRANTS** the Motion for Summary Judgment of Defendants Novus Scientific Pte. Ltd., Novus Scientific, Inc. and Novus Scientific AB as to Plaintiff Poly-Med's South Carolina Unfair Trade Practices Act Claim. (ECF No. 273.)

IT IS SO ORDERED.

J. Michelle Childs
United States District Judge

August 24, 2018
Columbia, South Carolina

[11] Because this failure to demonstrate actual damages is dispositive in the context of the elements of a SCUTPA claim, the court need not address the remaining elements of the cause of action.